

### **REMARKS/ARGUMENTS**

Claims 1-6, 8-12, 32, 33 and 39 are pending in the captioned application. Claims 7, 13-31, 34-38 and 40-47 have been withdrawn from consideration. Claims 1-6, 8-12, 32, 33 and 39 are under examination and have been rejected. The specification has been amended. The claims have been amended. These amendments do not introduce new matter. Applicants respectfully request that these amendments be entered. Applicants submit that the amendments and arguments presented herein clearly place the claims in allowable form. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

#### **Specification**

Applicants have amended the specification to delete the embedded hyperlinks and/or other forms of browser-executable code, in accordance with the Examiner's suggestions. Applicants have also amended the description of Figures 1B-1E to include sequence identifiers for the sequences shown in the Figures. Description of these sequences is also added in the specification. A revised sequence listing is submitted with the instant reply as well. Applicants respectfully request that the objections to the specification be withdrawn.

**Claim Rejections – 35 U.S.C. § 101/112 Utility Rejections**

Claims 1-6, 8-11, 32, 33 and 39 are rejected under 35 USC § 101 for, in the Examiner's view, lacking patentable utility. More specifically, the Examiner asserts that while the claimed invention has a credible utility, it is not supported by a specific or substantial utility or, in the alternative, a well-established utility. Applicants respectfully traverse this rejection for the reasons set forth below.

Applicants first note that the utility requirement of § 101 is met either if the claimed subject matter has a "well-established" utility, or if a substantial, specific, and credible utility is disclosed in the specification.

An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.*, properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). For example, "some uses can be immediately inferred from a recital of certain properties." *In re Folkers*, 344 F.2d 970, 974 (C.C.P.A. 1965) (explicitly undisturbed by *Brenner v. Manson*, 383 U.S. 519, 535 n.23 (1966) and *In re Kirk*, 376 F.2d 936, 949 (C.C.P.A. 1967) (Rich, J., dissenting)). In particular, when "newly discovered compounds [that] belong to a class of compounds, the members of which have become well recognized as useful for a particular purpose because of a particular property, the only reasonable conclusion is that the new compounds, also possessing that property, are similarly useful." *Folkers* at 975, *see also* MPEP 2107.02.

In the instant application, claimed subject matter comprises nucleotide sequences encoding a human POSH like protein, which is homologous to mouse POSH (Tapon et al., *EMBO J.* 17:1395-1404 (1998)), with 33 % amino acid identity and 49 % amino acid similarity over the length of the two proteins. p. 128 ll. 22-25 of the application.

POSH1 has been shown to participate specifically in the activation of the JNK pathway, leading to activation of gene expression in response to PDGF stimulation in COS cells (Tapon et al., *ibid*). Full-length POSH protein was found to activate the JNK cascade, but had no effect on actin reorganization (Tapon et al., *ibid*).

It was well established, before the application was filed, that one can use an oncogene or tumor suppresser gene in cancer diagnosis, prognosis, and in the development of therapeutics and treatment. The nucleotide sequences of these genes can be used as a reference to compare to gene sequences from patients or healthy individuals for mutation analysis, cancer diagnosis and prognosis. The sequences can be used as substrates on microarrays for expression analysis in cancer patients. The sequences can also be used as antisense inhibitors of the over-expressed genes in patients. The sequences can be used to produce proteins, antibodies or fusion proteins useful for the diagnosis and development of therapeutics as well. In addition, the nucleic acid sequences can be used to develop primers and probes, the primers can be used in PCR

amplification of fragments of the gene, while the probes can be used for expression analysis.

Because the claimed nucleic acid sequences of the instant application encodes a POSH like protein, Applicants respectfully submit the claimed nucleotide sequences of the instant application belong to a class of compounds, the members of which have well-established utility. Applicants respectfully submit that the claimed nucleotide sequences, which are also capable of these particular purposes, are similarly useful. According to the Federal Circuit, “[t]he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (emphasis added).

Claims 1-6, 8-11, 32, 33 and 39 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Examiner, since the claimed invention is not supported by a specific or substantial utility or a well-established utility, the disclosure also fails to enable one skilled in the art to make and use the invention.

Applicants respectfully traverse the rejection. Applicants respectfully submit that because the claims indeed display a well-established utility for the reasons advanced above, the derivative rejection for non-enablement would be in error if reasserted against these claims. Applicants respectfully request therefore that the rejection be withdrawn.

**Claim Rejections – 35 U.S.C. § 112 for Lack of Enablement**

Claims 1-6, 8-11, 32, 33 and 39 are further rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Specifically, the Examiner states that the “rejection is set forth with respect the claims encompassing nucleic acids encoding a polypeptide having ‘conservative amino acid substitutions’.” Applicants respectfully traverse this rejection.

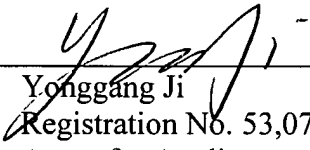
Solely for sake of expedition, however, and without admitting to the adequacy of the Examiner's *prima facie* case of unpatentability, Applicants have amended claim 1 to more clearly set forth the claimed invention. Applicants have deleted the phrase “with conservative amino acid substitutions” in claim 1. Applicants respectfully submit that in view of the above amendments to claim 1, the rejection should be withdrawn. Therefore, reconsideration is respectfully requested.

Applicants respectfully submit that the genera now claimed are fully supported by the specification and that the rejection should be withdrawn.

Early and favorable action is earnestly solicited.

Respectfully submitted,


AMERSHAM BIOSCIENCES CORP

By:   
Yonggang Ji  
Registration No. 53,073  
Agent for Applicants

Amersham Biosciences Corp  
800 Centennial Avenue  
P. O. Box 1327  
Piscataway, New Jersey 08855-1327

Tel: (732) 980-2875  
Fax: (732) 457-8463

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on February 18, 2005.

Signature: 

Name: Melissa Leck